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Overview

Registration Decision for (E,Z)-11-tetradecenal

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, has granted conditional registration for Materia Spruce Budworm Technical Pheromone, Bedoukian Spruce Budworm Technical Pheromone and Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant containing the technical grade active ingredient compound (E,Z)-11-tetradecenal to disrupt the mating of spruce budworm moths.

Current scientific data from the applicant, scientific reports and information from other regulatory agencies were evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This report summarizes the information that was evaluated and provides the results of the evaluation as well as the reasons for the registration decision, with an outline of the additional scientific information required from the applicant. It also describes the conditions of registration that the applicant must meet to ensure that the health and environmental risks as well as the value of these pest control products are acceptable for their intended use.

This overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Materia Spruce Budworm Technical Pheromone, Bedoukian Spruce Budworm Technical Pheromone and Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant containing (E,Z)-11-tetradecenal.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by Subsection 2(1) of the *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What is (E,Z)-11-tetradecenal?

(E,Z)-11-tetradecenal is the main component of the pheromone of spruce budworm moths. This pheromone is released by female spruce budworm moths and attracts males to the females for mating. The end-use product, Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant, contains the pheromone in micro-flake carriers which are applied with aerial application equipment.

Health Considerations

Can Approved Uses of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant Affect Human Health?

Spruce Budworm Technical Pheromone is unlikely to affect your health when Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is used according to the label directions

When assessing the health risks of the product Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant, two key factors are considered: the toxicity of the product and the levels to which people may be exposed.

The active ingredient, (E,Z)-11-tetradecenal, belongs to a group of compounds known as straight chain lepidopteran pheromones (SCLP). These pheromones are naturally occurring compounds that are produced by many lepidopteran insect species (i.e. moths and butterflies) to communicate chemically with other members of the same species. In general, SCLPs are biodegraded to non-toxic compounds by enzyme systems that are present in most living organisms. Toxicity studies on SCLPs have generally indicated no mammalian toxicity. The PMRA, United States Environmental Protection Agency (USEPA) and European Union regulatory authorities have received no reports of adverse effects to human health from the use of SCLPs.

Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is not formulated with any materials that are of toxicological concern nor are there any impurities that are of toxicological concern in the formulation.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Since there are no uses of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant on food or feed crops, the likelihood of residues contaminating food is negligible to non-existent.

Although the target application area of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is the upper canopy of forests and woodlots, it is reasonable to expect that small amounts of this product could be deposited on surface water. The risk from this contamination is not of concern because the amount of active ingredient entering the water system would be very small and it would quickly biodegrade to non-toxic compounds. Therefore, the possibility of contamination of potable water from residues or metabolites of this product is negligible to non-existent.

Occupational Risks From Handling Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant

Occupational risks are not of concern when Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is used according to label directions, which include protective measures.

Pesticide applicators mixing or loading Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant may come in direct contact with the product when loading the aerial application equipment. Therefore, the label specifies anyone mixing, loading, cleaning or repairing equipment should wear a long-sleeved shirt, long pants, chemical-resistant gloves and goggles. Taking into consideration these label statements and the low toxicity of this product, the risks to applicators, mixers or loaders are not of concern. The pilot of the aircraft is not expected to have any exposure to the end-use product during application.

Bystander exposure is possible, however, the highest application rate is 50 g of active ingredient (1 kg of product) per hectare and the target application area is the upper canopy of forests and woodlots. Since the areas of application are not commonly frequented by people and the product is not expected to reach ground level in significant quantities, the probability of accidental exposure is low. Considering the low toxicity and the low probability of exposure, the health risks to bystanders from the labelled use of this product are negligible to non-existent.

The postapplication exposure risks to human health are negligible since the level of active ingredient is not expected to exceed ambient levels of pheromone that would be produced by populations of spruce budworm moths during an infestation. No incidents of adverse affects to human health have been reported from exposure to ambient levels of SCLPs.

Environmental Considerations

What Happens When Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is Introduced Into the Environment?

Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is released into the environment from fixed-wing aircraft equipped with specialized pods or helicopters with pods or buckets. The pheromone active ingredient is volatile and as it is released from the micro-flake carriers will dissipate rapidly into the environment. Formulants present in the micro-flake carrier, upon release, are expected to have minimal environmental impact under the proposed use pattern

Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is to be broadcast applied in forested areas, thus, aquatic organisms and wild birds could be exposed through deposit in aquatic systems or ingestion of the micro-flake. Deposit of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant into aquatic systems is expected to be minimal, as a sticker agent is used to retain the micro-flake carriers in the plant canopy. A feeding study is being requested to further evaluate the risk to birds.

Value Considerations

What is the Value of (E,Z)-11-tetradecenal?

(E,Z)-11-tetradecenal, a pheromone from spruce budworm moths, can be used to disrupt adult spruce budworm moths from mating resulting in a decrease of fertile eggs being laid.

Numerous sources of (E,Z)-11-tetradecenal dispersed throughout a treatment area can interfere with the ability of male spruce budworm moths to locate female moths for mating. Female moths that remain unmated cannot produce and lay fertile eggs, therefore, damage from the subsequent generation of budworms is reduced. (E,Z)-11-tetradecenal is not a conventional insecticide and therefore is not expected to have any direct adverse effects on non-target organisms, including beneficial parasites and predators.

There are other pest control products currently registered for control of the spruce budworm in forests but (E,Z)-11-tetradecenal is a new alternative with a completely different mode of action that targets a different stage of the pest life cycle. Therefore, the use of (E,Z)-11-tetradecenal would reduce the possibility of spruce budworm developing resistance to the currently registered products and provide an additional strategy for integrated pest management of spruce budworm.

A key aspect of the value of this product is that Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant may be applied by air, providing a viable alternative for use in forests, where ground-based application would be impractical.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk reduction measures being proposed on the label of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Environment

Label statements specifying risk reduction measures which include avoiding application to aquatic systems are required.

What Additional Scientific Information is Being Requested?

Although the risks and value have been found acceptable when all risk reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation section of this Evaluation Report or in the Section 12 Notice associated with these conditional registrations. The applicant must submit the following information within the time frames indicated.

Chemistry

- The methods of analysis of the active ingredient and its impurities must be refined using a technique for standardization/calibration. This requirement may be addressed with either an analytical-grade standard of the active ingredient which is characterized with its purity and subsequently used for quantitation of the technical or an internal standard technique must be developed to accomplish the same goal. Submission of this information to the PMRA must be made no later than 1 August 2008.

Environment

- A laboratory feeding study is required to determine if birds will consume Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant when presented as food. Observations on the toxicity or other sublethal effects of the end-use product on the birds must also be reported. If the results indicate that Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is consumed by the test birds, then a limited scale monitoring study conducted under conditions of operational use in a spruce budworm control program may be required. Submission of this information to the PMRA must be made no later than 1 August 2008.

- In lieu of environmental fate data, a waiver request was submitted and reviewed by the PMRA. The actual study reports and papers published in scientific literature cited in this waiver are required. Submission of this information to the PMRA must be made no later than 1 August 2008.

Other Information

As these conditional registrations relate to a decision on which the public must be consulted[3], the PMRA will publish a consultation document when there is a proposed decision on applications to convert the conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

The test data cited in this Evaluation Report (i.e. the test data relevant in supporting the registration decision) will be made available for public inspection when the decision is made to convert the conditional registrations to full registrations or to renew the conditional registrations (following public consultation). If more information is required, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 28(1) of the *Pest Control Products Act*.

Science Evaluation

(E,Z)-11-tetradecenal

1.0 The Active Ingredient, its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance		(E,Z)-11-tetradecenal
Function		insect pheromone
Chemical name		
1.	**International Union of Pure and Applied Chemistry (IUPAC)**	(11E)-tetradec-11-enal (11Z)-tetradec-11-enal
2.	**Chemical Abstracts Service (CAS)**	(E)-11-tetradecenal (Z)-11-tetradecenal
CAS number		E-isomer: 35746-21-5 Z-isomer: 35237-64-0
Molecular formula		$C_{14}H_{26}O$
Molecular weight		210
Structural formula		
Purity of the active ingredient		Materia Inc.: 95.1% nominal (91E:9Z) Bedoukian Research: 98.0% nominal (95E:5Z)

1.2 Physical and Chemical Properties of the Active Substance and End-use Product

Technical Product—Materia Spruce Budworm Technical Pheromone and Bedoukian Spruce Budworm Technical Pheromone

Property	Result	
	Materia	Bedoukian
Colour and physical state	Colourless liquid	Clear liquid
Odour	Mild waxy odour	Mild odour
Melting range	N/A	N/A

Property	Result	
	Materia	Bedoukian
Boiling point	135°C at 0.3 mm Hg	100°C at 28 mm Hg
Specific gravity at 25°C	0.87–0.89	0.842–0.848
Vapour pressure at 25°C	<0.01 mm Hg	Not provided
Ultraviolet (UV)-visible spectrum	Not expected to absorb at λ >300 nm	Not expected to absorb at λ >300 nm
Solubility in water	Not soluble	Not soluble
Solubility in organic solvents	N/A - not to be mixed with nonpolar solvents	N/A - not to be mixed with nonpolar solvents
n-Octanol–water partition coefficient (K_{ow})	log K_{ow} = 6.99 (range 6.36–7.90)	Not provided
Dissociation constant (pK_a)	N/A - does not dissociate	N/A - does not dissociate
Stability (temperature, metal)	Stable to short-term elevated temperature, or if stored in a cool place under nitrogen and away from sunlight; incompatible with metal hydrides	Stable

End-use Product—Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant

Property	Result
Colour	N/A
Odour	N/A
Physical state	Solid
Formulation type	Slow-release generator
Guarantee	5.0% nominal (E:Z isomer ratio between 91:9 and 95:5)
Container material and description	Impermeable heat-seal polyethylene/polyester bags, or equivalent
Density	1.0 g/cm^3
pH of 1% dispersion in water	N/A

Property	Result
Oxidizing or reducing action	Does not contain oxidizing/reducing agents
Storage stability	Study not yet complete
Explodability	Not explosive

1.3 Directions for Use

Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is intended for use in reducing spruce budworm (*Choristoneura fumiferana* (Clemens)) damage in forests and woodlands by interfering with mating communication between adult moths. Disruption of the mating process may result in a decrease of fertile eggs being laid and, therefore, a decrease in subsequent larval infestation. This product is to be applied before or at the beginning of the male moth flight and is to be used on tree species such as white spruce where spruce budworm is a problem. The application rate of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is 25 to 50 g a.i./hectare. This is equivalent to 500 to 1000 g product/hectare. The higher application rate is recommended under higher pest pressure and may reduce the likelihood that re-application will be necessary. If re-application is determined to be necessary, based on local conditions, monitoring results and field scouting, the product may be applied 20 days after initial application. This product can be used in combination with supplemental sprays where populations are extremely high.

Use of an inert sticker such as Hercon® Micro-Tac™ is required to adhere the flakes to the treated foliage or plant parts. For application from fixed wing aircraft pods a ratio of 0.67 mL of sticker per 1 g of product is recommended.

1.4 Mode of Action

(E,Z)-11-tetradecenal is a pheromone attractive to male spruce budworm moths seeking females for mating. As a pest control product, (E,Z)-11-tetradecenal is incorporated into micro-flake carriers which are dispersed throughout the treatment area. The pheromone is released from the micro-flake carriers into the environment where the pheromone interferes with the ability of male moths to locate female moths. The precise mode of action for this mating disruption is unknown, but it may be behavioural (e.g. the males follow pheromone trails to the more numerous micro-flake carriers rather than to the females) or physiological (e.g. with so many sources of pheromone, the males' pheromone receptors become saturated and no longer respond).

2.0 Methods of Analysis

2.1 Methods for Analysis of the Technical Grade of Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Materia Spruce Budworm Technical Pheromone and Bedoukian Spruce Budworm Technical Pheromone have been partially validated. The registrants of the two technical products are required to refine these methods to improve the reliability of the quantitation.

2.2 Method for Formulation Analysis

The method provided for the analysis of the active ingredient in the formulation has been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for Residue Analysis

Not applicable as residues are not expected in the environment.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Reduced toxicological data requirements have been established for Straight Chain Lepidopteran Pheromones (SCLPs). SCLPs are poorly soluble in water and are biodegradable by enzyme systems present in most living organisms. SCLPs are products of fatty acid metabolism. Health studies have indicated that these substances pose minimal risks and provide effective pest control at low concentrations, similar to those occurring in nature.

The formulated product, Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant, is contained within a passive, gradual release dispenser, i.e. the micro-flake carrier. Therefore, the potential for direct human exposure to the formulation ingredients is considered to be negligible.

The applicant provided a rationale that requested all toxicological data requirements be waived because Spruce Budworm Technical Pheromone is an SCLP. Also, impurities and formulants contained in these pest control products are not of toxicological concern. The applicant`s rationale is acceptable and no further toxicological information or data are required.

Based on all of the available data for SCLPs, there is no evidence of increased susceptibility of infants and children in comparison to adults that may result from exposure to SCLPs. Furthermore, there is no evidence that SCLPs have a potential to disrupt endocrine activity in humans.

3.2 Acute toxicity—technical product and end use formulation; Genotoxicity—technical product

Data submitted to register other semiochemicals (most are SCLPs) in Canada and the United States have indicated no mammalian toxicity when mammals are exposed to high doses.

Available data indicate semiochemicals have low acute toxicity (LD_{50} > 5000 mg/kg), low acute dermal toxicity (LD_{50} > 2000 mg/kg), low acute inhalation toxicity (LC_{50} generally > 5 mg/L), no evidence of mutagenicity (Ames salmonella assay) and minimal eye and skin irritation. Published mammalian toxicity data on SCLPs indicate no significant acute toxicity to humans.

SCLPs are biodegradable by enzyme systems present in most living organisms. For example, the known metabolism of long chain fatty acids predicts that SCLPs would be metabolised either by β-oxidation yielding a series of paired carbon losses, or by complexing with glucuronide and excretion by the kidneys.

The formulants present in Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant are not of toxicological concern.

3.3 Acceptable Daily Intake and Acute Reference Dose Determination

Based on the chemical, physical, biological and toxicological properties of SCLP compounds, it is considered that they pose little or no risk of eliciting any adverse, toxicological effects. Data indicate that SCLPs pose a minor potential impact on human or animal health due to their low toxicity and use patterns. Adverse human health effects resulting from exposure to pheromone products have never been reported. Therefore, it is not considered necessary to establish an acceptable daily intake (ADI) or an acute reference dose (ARfD) for Spruce Budworm Technical Pheromone due to its inherent lack of toxicity and since it does not pose any significant residue concerns.

Spruce Budworm Technical Pheromone is not for use in or around food or feed.

3.4 Occupational and Bystander Exposure Assessment

The end-use product is formulated as a micro-flake carrier where two outer barrier films form a reservoir containing a layer of the technical product and other formulants. The pheromone contained in the technical product layer migrates to the edges of the micro-flake carrier permitting a gradual release into the atmosphere. The formulants in the technical product layer remain fixed between the outer barrier films. Each micro-flake carrier measures 2.4 mm × 0.8 mm. The application rate is 25–50 g a.i./ha. A repeat application may be made during the season.

Based on the toxicological profile of the active ingredient, a quantitative estimate of exposure was not required. Exposure is anticipated to be primarily dermal and could occur during mixing and loading of the end-use product. The precautionary label statements and required personal protective equipment, i.e. long-sleeved shirt, long pants, chemical resistant gloves and goggles are adequate to address worker exposure. Bystander and re-entry exposure is considered negligible.

Based on the toxicological profile of the active ingredient, it is concluded that the use of the end-use product is not likely to present a risk to workers or bystanders when it is used according to label directions.

3.5 Food Residues Exposure Assessment

As Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is not to be applied in or around food or feed crops, a food residue assessment was not required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The active ingredient in Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is a pheromone and, thus, is volatile. As the active ingredient is released from the micro-flake carrier, it will dissipate rapidly in the environment.

The applicant submitted a waiver request for Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant. The waiver consisted of a summary of information on the fate of formulants present in the micro-flake carrier in simulated landfills and information that examined the bioaccumulation potential of these formulants. A formulant potentially released from the micro-flake carrier is reported as having very low solubility in water and preferential binding to soil and is not expected to leach. The formulants present in the micro-flake carrier, upon release, are expected to have minimal environmental impact under the proposed use pattern

The actual study reports and the papers published in scientific literature cited in the waiver request were not provided to the PMRA. As a result, all supporting information cited in the waiver must be provided to the PMRA.

4.2 Effects on Non-Target Species

The applicant submitted a waiver for an acute toxicity study of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant to birds and fish. The waiver was based on the rationale that the active ingredient, (E,Z)-11-tetradecenal, is a straight chain lepidopteran pheromone which is not of toxicological concern to mammals or fish and, therefore, is not likely to pose a risk to birds. The applicant also stated, based on submitted data, that the micro-flake carrier used in Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant was not toxic to mammals (based on rats as a test species) or aquatic invertebrates (using *Daphnia* spp. as a test species) and, therefore, not likely to be of concern to birds and fish.

It was also stated that the proposed rate of application of the product, the small size, the texture and the placement of the micro-flake carriers in the upper-mid tree canopy indicated that it was highly unlikely that a bird or fish would ingest the Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant or otherwise be exposed to it. The PMRA has determined the active ingredient (E,Z)-11-tetradecenal will not pose an appreciable risk to birds and fish, when used according to the proposed label. However, the PMRA does have concerns regarding the potential impact of the micro-flake carriers on birds that may mistake these as food items (refer to Section **Exposure and PMRA Risk Assessment**).

Exposure and PMRA Risk Assessment

The rate of application is a maximum of 1.0 kg end-use product/ha, indicating a low amount of product will be dispersed per unit area. In addition, a sticking agent is used in conjunction with the end-use product, thus the end-use product will be intercepted by foliage and other vegetation.

Based on the application methods, exposure of non-target aquatic organisms in forested areas will be limited. If, however, the product is applied to areas with aquatic systems and without sufficient plant canopy, then exposure of aquatic organisms to Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant (e.g. ingestion by fish) could occur. Under such circumstances, concentration of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant in water would be expected to be very low and, therefore, minimal risk to aquatic organisms would be expected. To further mitigate potential risk, label statements indicating application to aquatic environments is to be avoided are required on the label.

It is unclear if wild birds will consume Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant under field conditions or if ingestion of the end-use product would cause adverse effects. Wild birds may mistake Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant for their usual food sources, such as seeds or small insects. Laboratory studies or field monitoring of birds in the area of treatment may address this uncertainty of exposure.

A feeding study in the laboratory is required to determine if birds will consume Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant presented as food. Observations on the toxicity or other sublethal effects of the end-use product on the birds must also be reported. If the results indicate that Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant are consumed by the test birds, then a limited scale monitoring study conducted under conditions of operational use in a spruce budworm control program may be required.

5.0 Value

5.1 Effectiveness Against Pests

Efficacy data were submitted from two field trials conducted in Simcoe County, Ontario, in 2004 and 2005. The 2004 trial compared application rates of 15 and 50 g a.i./ha and the application rate in the 2005 trial was approximately 25 g a.i./ha. No re-applications were made and results were assessed up to 20 days after treatment. Mating disruption was achieved in 2004 with the higher application rate, 94% of caged females and up to 73% of wild females remaining unmated compared to only 13% of caged females and 1% of wild females remaining unmated in the

untreated control. The lower application rate was less effective, with 41% of caged females and a maximum of 42% of wild females remaining unmated. Egg mass deposition was reduced substantially with the higher application rate (0.4–4.4 egg masses per branch) compared to the lower application rate (4.0–21.4 egg masses per branch). Although data from the 2005 trial were more limited, these data indicated that 25 g a.i./ha may be nearly as effective as 50 g a.i./ha but for a shorter period of time.

5.1.1 Acceptable Efficacy Claims

The submitted efficacy data support the use of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant for mating disruption of the spruce budworm by aerial application to forests and woodlands at the rate of 0.5–1.0 kg end-use product/hectare (25–50 g a.i./ha) at the beginning of the adult moth flight period with re-application after 20 days if necessary.

5.2 Phytotoxicity to Host Plants

Phytotoxicity was not assessed but is not expected as the active ingredient is not applied directly to the host trees but is released by volatilization from the micro-flake carriers.

5.3 Impact on Succeeding Crops

Considering the nature of the product and the long rotation times for forest tree crops, no impact on succeeding crops is expected.

5.4 Economics

No market analysis was provided for this product evaluation, however, there are few alternatives registered for control of the spruce budworm. Historically, spruce budworm is the most destructive pest of coniferous forests in eastern Canada and is distributed throughout the boreal forest as far west as northeastern British Columbia and Yukon.

5.5 Sustainability

5.5.1 Survey of Alternatives

The only alternative pest control products currently registered for control of spruce budworm in forests are products containing the active ingredients tebufenozide (an insect growth regulator) or *Bacillus thuringiensis* subsp. *kurstaki* (a microbial insecticide). Both of these active ingredients target the larval stage of the pest (see Table 1, Appendix I).

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

(E,Z)-11-tetradecenal is currently used in trap lures for monitoring populations of spruce budworm. Population monitoring using pheromone-baited traps may not be possible in areas treated with (E,Z)-11-tetradecenal for mating disruption, or may require trap lures containing larger doses of pheromone to be effective, further research would be required to address this point. Otherwise, (E,Z)-11-tetradecenal is entirely compatible with current management practices including integrated pest management, for which it provides an additional strategy with an alternative mode of action that targets a different life stage of the pest.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

It is conceivable that resistance to the pest management strategy of mating disruption could evolve through shifts in the composition of the pheromone and corresponding shifts in the response of the male moths, but this is generally considered unlikely. It is especially unlikely for a widely distributed species such as spruce budworm, with only a very small portion of the population being exposed to the mating disruption, to be subjected to sufficient selection pressure to alter their pheromone communication system.

5.5.4 Contribution to Risk Reduction and Sustainability

(E,Z)-11-tetradecenal contributes to risk reduction and sustainability by providing a low risk alternative with a different mode of action from the currently registered products, thereby, increasing the range of options for integrated pest management.

6.0 Formulant and Microcontaminants of Health or Environmental Concern

6.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's Toxic Substances Management Policy (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track-1 substances.

During the review process, the active ingredient (E,Z)-11-tetradecenal was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of (E,Z)-11-tetradecenal were also considered, including major transformation products formed in the environment, microcontaminants in the technical products and formulants in the end-use product, Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant. The PMRA has reached the following conclusion:

- It has been determined that this technical product does not meet TSMP Track-1 criteria on the grounds of non-persistence, no bioaccumulative potential, and low toxicity.

Therefore, the use of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is not expected to result in the entry of Track-1 substances into the environment.

6.2 Formulants of Health Concern

- The technical products containing (E,Z)-11-tetradecenal, Materia Spruce Budworm Technical Pheromone and Bedoukian Spruce Budworm Technical Pheromone do not contain any contaminants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

- The end-use product, Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant, does not contain any formulants of health or environmental concern identified in the *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

7.0 Summary

7.1 Human Health and Safety

(E,Z)-11-tetradecenal belongs to a group of compounds called Straight Chain Lepidopteran Pheromones (SCLPs), that have been well characterized. SCLPs have been shown to have no mammalian toxicity. They are readily metabolized by most organisms and no adverse health effects of SCLPs have been reported.

Mixer, loader and applicators are not expected to be exposed to levels of (E,Z)-11-tetradecenal that will result in unacceptable risk when the end-use product is used according to label directions. The personal protective equipment on the product label is adequate to protect workers and no additional personal protective equipment is required.

Residues of (E,Z)-11-tetradecenal are not expected to occur on food or feed.

7.2 Environmental Risk

Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant is to be broadcast applied in forested areas, thus, there could be potential exposure to aquatic organisms and wild birds primarily through ingestion of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant deposits in aquatic systems or on land and in trees. Deposits of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant into aquatic systems is expected to be minimal as a sticker agent is used to retain Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant in the plant canopy. Birds could consume Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant if mistaken for a food item, therefore, a bird feeding study is required. As the active ingredient is a pheromone and is highly volatile it will dissipate rapidly once released, thus exposure of non-target organisms to the released pheromone is not a concern.

7.3 Value

The data submitted in support of registration of Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant demonstrate this product has value in disrupting mating of the spruce budworm and reducing subsequent egg mass deposition.

7.4 Unsupported Uses

The applicant originally proposed application rates ranging from 15 to 50 g a.i./ha and a re-application interval of 30–45 days.

The submitted efficacy data supported the application rate range of 25–50 g a.i./ha and a re-application interval of 20 days, if necessary, based on monitoring.

8.0 Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, has granted conditional registration for the sale and use of the Materia Spruce Budworm Technical Pheromone, Bedoukian Spruce Budworm Technical Pheromone and Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant containing the technical grade active ingredient compound (E,Z)-11-tetradecenal to disrupt the mating of spruce budworm moths.

An evaluation of current scientific data from the applicant, scientific reports and information from other regulatory agencies has resulted in the determination that, under the approved conditions of use, the end-use product has value and does not present an unacceptable risk to human health or the environment.

Although the risks and value have been determined to be acceptable when all risk reduction measures are followed, as a condition of these registrations, additional scientific information is being required from the applicant as a result of this evaluation. (For more details, refer to the Section 12 Notice associated with these conditional registrations.)

NOTE: The PMRA will publish a consultation document at the time when there is a proposed decision on applications to convert these conditional registrations to full registrations or on applications to renew the conditional registrations, whichever occurs first.

Chemistry

- The methods of analysis of the active ingredient and its impurities must be refined using a technique for standardization/calibration. This requirement may be addressed with either an analytical-grade standard of the active ingredient which is characterized with its purity and subsequently used for quantitation of the technical or an internal standard technique must be developed to accomplish the same goal. Submission of this information to the PMRA must be made no later than 1 August 2008.

Environment

- A laboratory feeding study is required to determine if birds would consume Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant when presented as food. Observations on the toxicity or other sublethal effects of the end-use product on the birds must also be reported. If the results indicate that Hercon Disrupt Micro-Flake SBW Spruce Budworm Mating Disruptant are consumed by the test birds, then a limited scale monitoring study conducted under conditions of operational use in a spruce budworm control program may be required. Submission of this information to the PMRA must be made no later than 1 August 2008.

- In lieu of environmental fate data, a waiver request was submitted and reviewed by the PMRA. The actual study reports and papers published in scientific literature cited in this waiver are required. Submission of this information to the PMRA must be made no later than 1 August 2008.

List of Abbreviations

a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
BCF	bioconcentration factor
DEHP	di(2-ethylhexyl)-pthalate
g	gram
ha	hectare(s)
Hg	mercury
K_{ow}	*n*–octanol-water partition coefficient
kg	kilogram
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
mg	milligram
mL	millilitre
mm	millimetre
N/A	not applicable
PMRA	Pest Management Regulatory Agency
pKa	dissociation constant
PVC	polyvinyl chloride
SBW	spruce budworm
SCLP	straight chain lepidopteran pheromone
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I

Table 1 Alternative Active Ingredients Registered for Control of Spruce Budworm in Forests

Active Ingredient	Insect Control Claims	Classification	Comments
Bacillus thuringiensis subsp. *kurstaki*	Bagworm Eastern hemlock looper Eastern spruce budworm Elm spanworm Fall cankerworm Fall spanworm Forest tent caterpillar Gypsy moth Jack pine budworm Satin moth Spring cankerworm Western hemlock looper Western spruce budworm Whitemarked tussock moth	Group 11 Insecticide	Several end-use products are registered for this use pattern, but not all for the same range of insect pests.
Tebufenozide	Eastern spruce budworm Hemlock looper Jack pine budworm Whitemarked tussock moth	Group 18 Insecticide	A single end-use product is registered for this use pattern.

Table 2 Use Claims Proposed by Applicant and Whether Acceptable or Unsupported

Applicant-Proposed Claims	Acceptable Claims	Unsupported Claims and Comments
Mating disruptant for the spruce budworm, *Choristoneura fumiferana* (Clemens).	Mating disruptant for the spruce budworm, *Choristoneura fumiferana* (Clemens).	Accepted as proposed.
Application rate 15–50 g a.i. (300–1000 g product) per ha.	Application rate 25–50 g a.i. (500–1000 g product) per ha.	Efficacy data did not support the lower application rate of 15 g a.i./ha.
Reapply after 30–45 days.	Reapply after 20 days, if necessary.	Efficacy was not assessed beyond 20 days after application.

List of References

A. List of Studies/Information Submitted by Registrant

1.0 The Active Ingredient, Its Properties and Uses

PMRA 1147622 2006, SBW Pheromone Appendix A MSDS, N/A, MRID: N/A, DACO: 2.16

PMRA 1217119 2006, Materia SBW Pheromone Product Chemistry 040706, N/A, MRID: N/A, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.12.1,2.13.2,2.13.3,2.13.4

PMRA 1217120 2006, Supplemental Product Chemistry Materia SBW Technical Technical Precision and Accuracy, N/A, MRID: N/A, DACO: 2.13.1,2.13.2,2.14.14

PMRA 1316020 2006, Materia SBW Technical Pheromone Product Chemistry 10.05.06, 10.05.06, MRID: N/A, DACO: 2.11,2.11.2,2.11.3,2.11.4,2.12,2.13.1,2.13.2,2.13.3

PMRA 1412466 2007, SBW Pheromone Product Chemistry 032307, N/A, MRID: N/A, DACO: 2.13.1,2.14

PMRA 1412467 2007, Response to PMRA Questions March 23 2007, N/A, MRID: N/A, DACO: 2.13.1,2.13.3

PMRA 1412469 2007, Response to PMRA March 29 2007, N/A, MRID: N/A, DACO: 2.13.2

PMRA 1147651 2006, DACO 2.1 to 2.9, N/A, MRID: N/A, DACO: 2.1,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9

PMRA 1147652 2005, P6045-95 Manufacture Process, N/A, MRID: N/A, DACO: 2.11.1,2.11.2,2.11.3,2.11.4

PMRA 1147654 2005, Analytical Method for TGAI SBW Pheromone, N/A, MRID: N/A, DACO: 2.13.1

PMRA 1147655 2005, Spruce Budworm TGAI Chromatograph, N/A, MRID: N/A, DACO: 2.13.2

PMRA 1147657 2006, DACO 2.14 Physical and Chemical Properties, N/A, MRID: N/A, DACO: 2.14.1,2.14.13,2.14.2,2.14.3,2.14.4,2.14.6,2.14.7,2.14.8,2.14.9

PMRA 1315940 2006, 2.11.2 Description of Starting Materials, N/A, MRID: N/A, DACO: 2.11.2

PMRA 1315941 2006, 2.11.3 Production Process Description, N/A, MRID: N/A, DACO: 2.11.3

PMRA 1315942 2006, 2.11.4 Formation of Impurities, N/A, MRID: N/A, DACO: 2.11.4,2.13.4

PMRA 1315943 2006, 2.13.1 Methodology and Validation, N/A, MRID: N/A, DACO: 2.13.1,2.13.2

PMRA 1315944 2006, 2.13.3 Batch Data Summary Table, N/A, MRID: N/A, DACO: 2.13.3

PMRA 1315945 2006, 2.13.3 Batch Data Chromatograms, N/A, MRID: N/A, DACO: 2.13.3

PMRA 1412483 2007, Analysis of Spruce Budworm Pheromone and its 2 impurities, N/A, MRID: N/A, DACO: 2.13.1,2.13.2

PMRA 1412485 2007, 2006-0609 March 29 2007 response to PMRA, N/A, MRID: N/A, DACO: 2.13.1,2.13.2,2.14

PMRA 1412486 2007, 2.13.2 Linearity data plus impurities 2006-0609, N/A, MRID: N/A, DACO: 2.13.2

PMRA 1159343 2005, Part 3 EP Chemistry, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.2.1,3.2.2,3.3.1,3.4.1,3.5.1,3.5.10,3.5.2, 3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8

PMRA 1315997 2006, Method Validation for Analytical Method No.HX00118 Disrupt MF SBW, DACO: 3.4.1

PMRA 1315994 2006, 2006-0610 Cover letter Hercon Response to Deficiency, DACO: 0.8

2.0 Impact on Human Health

PMRA 1159344 2006, DACO 4.1 Summary, DACO: 4.1

PMRA 1159345 1975, DACO 4.61 Acute Oral Vinyl Study

3.0 Impact on the Environment

PMRA 1159348 2006. DACO 8.1 Summary. Submitted by the applicant.

PMRA 1159349 2006. DACO 9.1 Summary. Submitted by the applicant.

PMRA 1159350 2005. Standard Flake Test. A summary of a non-GLP/QA/QC study prepared by Wildlife International Ltd. 4 pp.

PMRA 1159351 2006. Waiver request for DACO 9.5 (Fish). Submitted by the applicant.

PMRA 1159352 2006. Waiver request for DACO 9.5 (Birds). Submitted by the applicant.

4.0 Value

PMRA 1159357 Development of a Pheromone Formulation for Use in Early Intervention Pest Management Strategies of the Spruce Budworm, *Choristoneura fumiferana* (Clem.); SERG-I Project 614; Final Report, February 2005, DACO: 10.2.3.4

PMRA 1315999 Tables 1,2,3 Mating Status SBW BLP 2004, DACO: 10.2.3.4(D)

PMRA 1316000 Results of Aerially Applied Disrupt Microflakes on Spruce Budworm Mating Success, Ontario, 2005; October 2006, DACO: 10.2.3.4(D)

B. Additional Information Considered

I. Published Information

PMRA 1413251 2002, ENVIRONMENT DIRECTORATE, JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY. Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control. OECD